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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,112	05/25/2001	Philippe Benaroch	24190.0003	8305

23767 7590 08/06/2004

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	19

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,112	Applicant(s) BENAROCH ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-59* is/are pending in the application.

4a) Of the above claim(s) *1-11,16-31,33-51 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,15,32,52-56,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/FR99/02691.

Claims 13 and 14 have been canceled.

Claims 1-12 and 15-59 are currently pending.

Election/Restrictions

1. Claims **1-11, 16-31, 33-51 and 57 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Accordingly, **claims 12, 15, 32, 52-56, 58 and 59 are the subject of examination** in the present Office Action.

In view of Applicant's amendment filed December 23, 2003, a courtesy copy of which was filed May 11, 2004, only the following grounds of rejection are maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12, 15, 32 and 52 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tuck et al (Blood (1994) 84(7):2182-2188; U on form PTO-892).

It was previously stated: "The Tuck reference teaches isolated membrane-derived vesicles that were shed from COS-1 cells and comprised recombinantly produced heterologous molecules of interest [Claim 12]. Tuck teaches that one heterologous molecule of interest in the vesicles was macrophage colony stimulating factor (M-CSF), a peptide molecule [claim 13], which is a pharmacological product [claim 14], as it exerts an affect on macrophages. Tuck also teaches that the vesicles were negatively stained for electron micrographic analysis with phosphotungstic acid (page 2183, paragraph bridging columns in particular), a second heterologous molecule of interest [claim15], which is a chemical substance deposited directly on the vesicles in accordance with the instant specification at page 14, lines 12-24 for example. Tuck further teaches the M-CSF was membrane bound on the vesicles shed into the culture supernatant [claim 52]. Tuck also teaches a composition consisting essentially of conditioned medium comprising the M-CSF-bearing vesicles [claim 32]. While Tuck does not specifically teach that the isolated vesicles are mastocyte-derived, absent a showing to the contrary regarding specific properties not present in vesicles derived from other sources, membrane vesicles derived from mastocytes are not seen as being different from vesicles derived from other eukaryotic cell types. The instant claims are

product claims drawn to the end product, the isolated vesicle, not the starting material and mastocytes merely represent a preferred starting material which are used to produce an end product which is materially indistinct from isolated vesicles produced by other eukaryotic cells. The prior art anticipated the claimed invention."

Applicant's arguments filed December 23, 2003 have been fully considered but they are not persuasive.

Applicant argues that Tuck cannot be considered anticipatory because Tuck teaches eukaryotic vesicles derived from transfected COS-1 cells and the instant claims are drawn to eukaryotic vesicles derived from mastocytes and are therefore different. In support of this position, Applicant cites a passage from Tuck in which the author acknowledges that vesicles derived from different cell types may be different and it is unknown whether the recombinant COS-1 vesicles are the same as other vesicles. However, the fact that Tuck did not know whether the activity of the COS-1 vesicles is the same for all vesicles is not proof of the Tuck vesicles being different from the instantly disclosed and claimed vesicles. Silence about a property does not necessarily constitute its absence and the vesicles of Tuck, in spite of being derived from a different source cell, may still be the same as the instant vesicles. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 12, 53-56, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuck et al (Blood (1994) 84(7):2182-2188; U on form PTO-892) in view of Xu et al (Molec. Immunol. (1994) 31(10):723-731; V on form PTO-892).

Tuck has been discussed supra. Tuck further teaches that MHC Class I and Class II molecules may also be borne on membrane fragments such as isolated vesicles to effect intracellular functionality (page 2182, paragraph bridging columns in particular).

Tuck et al does not specifically teach recombinant MHC Class II molecules of the DR1 serotype. Xu teaches the recombinant expression of HLA DR1 α and β chains in COS-1 cells (see entire reference)[claims 53-56 and 58-59]. It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to combine the teachings of Xu regarding the recombinant expression of DR1 α and β chains with the teachings of Tuck to study the interaction of vesicle-bound MHC molecules with effector CD4+ T cells. One would have been motivated to combine the references with a reasonable expectation of success based upon the showing of Xu that DR1 α and β chains can be recombinantly expressed in the same type of cells as those used in the Tuck reference and the teachings of Tuck that vesicle-bound MHC molecules may stimulate T cells in a manner similar to stimulation of T cells by direct physical contact of antigen presenting cells (page 2182, paragraph bridging columns in particular) and the suggestion that the cell surface can play a role in transmitting a signal, whether by direct cell-cell interaction or by interaction of a vesicle with the effector cell (page 2187, last paragraph in particular).

Applicant argues that Xu does not correct the deficiencies in Tuck because Xu does not teach or suggest membrane vesicles expressing recombinant MHC class II molecules. However, Xu does teach the successful recombinant expression of MHC class II in COS-1 cells, as used by Tuck. Further, as explained previously, "Tuck further teaches that MHC Class I **and Class II molecules may also be borne on membrane fragments such as isolated vesicles** to effect intracellular functionality" (emphasis added). Accordingly, Tuck teaches that membrane fragments, such as vesicles, can express functional MHC class II molecules and Xu teaches that functional MHC class II can be expressed in COS-1 cells. Accordingly, the combined teachings would have provided the artisan with the information needed to create recombinant MHC class II-bearing vesicles from COS-1 cells.

Conclusion

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
July 27, 2004